

REMARKS

Claims 157-213 were pending. New claims 214-229 have been added. Therefore, claims 157-229 are currently pending. Support for the new claims is found throughout the specification, for example in the examples, especially Example 23, and the original claims. Therefore, no new matter has been added.

The Applicants thank the Examiner for the time and courtesy extended during the interview on Tuesday, October 5th, 2010. During the interview, Applicants contended that the current restriction requirement makes it unclear what subject matter the Examiner is asserting is patentably distinct in Groups I-IV, and given the structural similarity of the stabilized compositions of claim 158 (Group I), claim 159 (Group II), claim 160 (Group III) and claim 161 (Group IV), the restriction is improper and should be at the least modified.

As stated during the interview, Applicants would not be adverse to a restriction based on the various classes of stabilizers recited in claim 1. In response to such a restriction, Applicants would be willing to limit the claims to the first listed class of stabilizers: a stabilizer comprising a water-soluble organic compound containing selenium in the +2 oxidation state and would elect a species if requested. No compromise was reached during the interview.

Restriction and Election of Species Requirement

The Examiner has required restriction of claims 157-213 under 35 U.S.C. § 121. More specifically, the Examiner has required restriction to one of nine (9) groups, as described below:

Group I	Claims 157,158, 162-174, and 182-188.
Group II	Claims 159 and 162-174, drawn to compositions comprising a chelator, radionuclide, and targeting agent.

Group III	Claims 160, 162-174, 189-192, and 200-213, drawn to compositions comprising a metal chelator, targeting molecule
Group IV	Claims 161-174, and 189-192, drawn to compositions comprising a metal chelator, targeting molecule, and stabilizer having at least one bile acid.
Group V	Claims 175-181, drawn to a method of stabilizing a radiopharmaceutical wherein the composition comprises a radionuclide, chelator, and stabilizer.
Group VI	Claims 193 and 194, drawn to a method of increasing radioactivity recovery.
Group VII	Claims 195 and 196, drawn to a method of decreasing methionine residues.
Group VIII	Claims 197 and 199, drawn to a method of reducing metallic contaminant interference.
Group IX	Claims 198 and 199, drawn to a method of improving radiopharmaceutical yield.

With respect to the restriction requirement, applicants hereby elect, without traverse, and solely to speed prosecution, the claims of Group VI, namely Claims 193 and 194.

Applicants respectfully traverse the restriction requirement. Applicants note that Groups I to IV are all directed to compositions and include overlapping subject matter; thus it is unclear what the Examiner regards as the patentably distinct subject matter in these claims.

Notwithstanding the definitions of the various Groups in the Office Action, each of Groups I-IV includes claims that require a radiopharmaceutical composition and a stabilizer wherein the radiopharmaceutical comprises a radionuclide, a chelator and a targeting molecule (see e.g. claims 158,159, 160 and 161 in Groups I, II, II and IV, respectively). Thus, each of these claims is directed to a structurally similar stabilized radiopharmaceutical composition. Furthermore, the Examiner's reference to "a stabilizer having at least one non-alpha amino acid with a cyclic group present" in Group II and "a stabilizer having at least one bile acid" in Group III evidences a misunderstanding of the claimed invention. The inventions of Groups I-IV are stabilized radiopharmaceutical compositions comprising one of various classes of stabilizers and a radionuclide, which is optionally complexed with a chelator, a linker and a targeting molecule. The claims of Groups II and IV simply specify that the linker is present and includes either a non-alpha amino acid with a cyclic group or a bile acid – they do not require that the stabilizer includes either a bile acid or a non-alpha amino acid with a cyclic group.

However, in order to provide a complete response Applicants must provide an election. Applicants submit that given the issues identified above with Groups I-IV none of these groups could be elected. Thus, Applicants elect Group VI, claims 193-194 with traverse. Applicants submit that new claims 214-229, which depend from claim 193 should also be included in Group VI. Applicants elect the species of claim 217 complexed with the radionuclide ¹⁷⁷Lu, in which the benzyl alcohol is reacted with the radiolabeled chelate with traverse as well. The elected species read on claims 193-194 and new claims 214-229.

It is Applicant's understanding that this species election is for searching purposes only and upon a finding of allowability of the elected species, the remaining species will also be searched. Applicants further understand that upon the allowance of a generic claim, they will be

entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R.

§1.141.

No fee is believed to be due with the filing of this Amendment. However, if any fee is due, the Director is hereby authorized to charge any additional deficiencies or credit any overpayments to Deposit Account No. 50-0540.

Respectfully submitted,

Date: October 12, 2010

/Ilona Gont/
Ilona Gont , Reg. No. 58,714.
Donald L. Rhoads, Reg. No. 34,705.
Kramer Levin Naftalis & Frankel LLP
1177 Avenue of the Americas
New York, N.Y. 10036
(212) 715-9100 (telephone)
(212) 715-8000 (facsimile)